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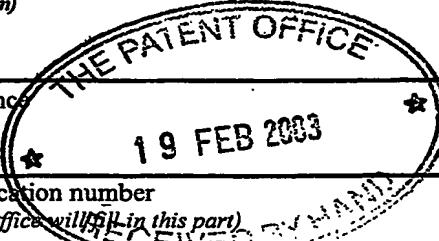
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P0332759B

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0303821.3

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JOHNSON & JOHNSON MEDICAL LIMITED
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UNITED KINGDOM

Patents ADP number (*if you know it*)

600 8031002

If the applicant is a corporate body, give the country/state of its incorporation

United Kingdom (Scotland) 

4. Title of the invention

FLUID WOUND DRESSING

5. Name of your agent (*if you have one*)

Carpmaels & Ransford

"Address for service" in the United Kingdom to which all correspondence should be sent (*including the postcode*)

43 Bloomsbury Square
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Patents ADP number (*if you know it*)

83001

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Country

Priority application number
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USA

60/421,085

25/10/2002

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Signature

Carpmael - Ransford
Carpmael & Ransford

Date

19th February 2003

12. Name and daytime telephone number of person to contact in the United Kingdom

DR. ANTHONY JAMES

020-7242 8692

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DUPPLICATE

1

FLUID WOUND DRESSING

The present invention relates to fluid wound dressings that can be used to fill cavity wounds.

5

Cavity wounds can be a problem to treat due to high levels of exudate production, the irregular contours of the wound site, the loss of tissue (sometimes undermining the surrounding skin) and the potential for tracts or sinuses. The full extent of the cavity wound is not always obvious from a visual assessment, which complicates

10 the treatment choice.

The main wound management regime for cavity wounds is much the same as for other wounds, that is to say moist wound healing and exudate management. The standard treatments tend to be based around packing the cavity with gauze, 15 alginates or some other absorbent material. This primary dressing is often held in place with a secondary dressing, such as a film, foam or gauze, depending on the level of exudation.

The extent to which a cavity wound is packed is determined by the caregiver and 20 should be dependent on the packing material. There is a tendency to over-pack cavity wounds, which may result on detrimental pressure being applied to the wound bed.

The care giver also needs to ensure that all of the cavity wound dressing is 25 removed after treatment, unless the dressing is fully bioresorbable.

Cavity wounds can be heavily exuding, and it is therefore desirable to use a cavity wound filling material that can transport material by capillary action or diffusion from the wound site to a moisture-absorbent secondary dressing.

30

It is known to provide textile or foam-based absorbent structures for dressing deep wounds. Those structures are insufficiently conformable to fit every deep wound, unless they are cut into shape. Furthermore, such absorbent structures can be

relatively difficult to remove from a deep wound after use without causing further trauma.

US-A-4837285 describes the use for soft tissue cavity filling of resorbable collagen
5 sponge beads having diameters of from 0.1 to 4.0 mm. The beads have pore sizes of from 50 to 350 micrometers. Such beads can be difficult to handle, and are not suitable for use as a removable, absorbent dressing for deep wounds.

DE-A-4037931 describes a deep cavity wound dressing structure consisting of a
10 cavity-filling plug of resorbable collagen foam containing an array of hollow resorbable filaments. The filaments are bundled together at one end, and connected to a drain for wound fluid, whereby the wound fluid is continuously drained from the wound cavity through the hollow filaments. Such a structure is relatively expensive to construct, and insufficiently conformable to a wide range of
15 wound cavity shapes.

EP-A-0171268 describes absorbent, non-adherent wound dressings for use in the treatment of deep wounds, wherein the dressing comprises a porous bag containing individual pieces of a conformable, resilient, absorbent hydrophilic
20 foam. The porous bag may be provided with a string to assist removal of the bag from the wound after use. This structure may be insufficiently conformable to a wide range of wound cavity shapes.

The present invention provides a wound dressing composition comprising a
25 partially cured polyurethane fluid.

The term "wound dressing composition" refers to a composition suitable for injection directly into wounds to provide a dressing for the wound. It does not encompass hardening compositions for orthopedic casts or the like. The term
30 "polyurethane" in this specification encompasses polymers comprising urethane and/or urea linkages.

The wound dressing according to the present invention is a fluid. The fluid may be a liquid, preferably a viscous liquid, or it may be a paste, or it may be a non-Newtonian fluid. This property makes the wound dressing composition especially suitable for completely filling a cavity wound by injection or pouring, or simply by 5 working the fluid into the wound cavity in with a spatula or similar implement.

The wound dressing composition comprises a partially cured polyurethane fluid. Preferably, it comprises at least 50% by weight of the polyurethane components, and more preferably at least 75%, 90%, or 95% by weight of the polyurethane 10 components. The polyurethane fluid is partially cured. That is to say, it has been prepared by mixing a diisocyanate or a polyisocyanate composition with a curing composition, such as a diol or polyol composition, but the reaction between the components has not gone to completion. For example, at least 1% of the isocyanate groups originally present in the isocyanate composition may still be 15 present (i.e. unreacted) in the wound dressing, preferably at least 10% thereof may still be present, and typically from 20% to 75% are still present. However, it should be noted that preferably the absolute amount of unreacted isocyanate in the wound dressing composition is low, in order to reduce adverse reaction of isocyanate *in vivo*. Preferably, the absolute amount of unreacted isocyanate 20 present in the composition according to the invention is less than about 4wt.% (i.e. about 1meq NCO/gram), more preferably less than about 2wt.%, and most preferably from about 0.1wt.% to about 1 wt.%.

Suitable components for the preparation of wound dressing compositions 25 according to the present invention are described below in connection with the third aspect of the present invention.

The polyurethane fluid starts to cure on mixing of the two components and continues to cure *in situ* in the wound to form a wound filling dressing that 30 conforms exactly to the shape of the wound. The resulting cured polyurethane is preferably soft and flexible for comfort, but preferably has sufficient wet and dry tensile strength to be removed in one piece from the wound after use. Preferably, the dry tensile strength of the as-cured polyurethane is at least about 5N/cm²,

more preferably at least about 10N/cm². Preferably, the wet tensile strength after immersion in physiological saline for 24 hours at 25C is at least 50% of the dry tensile strength, more preferably at least 75% of the dry tensile strength.

- 5 The cured polyurethane is preferably sufficiently hydrophilic to wick exudate from the wound to a secondary dressing, but preferably does not absorb enough wound fluid to give rise to swelling that would exert undesirable pressure. Preferably, the absorbency of physiological saline at 25°C after 24 hours is less than 200wt.% based on the weight of the as-cured polyurethane, more preferably less than
- 10 100wt.%.

In certain embodiments the wound dressing composition comprises additives, for example selected from the group consisting of humectants, plasticisers, hydrocolloids, blowing agents, medicaments, siloxane wetting agents and mixtures
15 thereof.

The optional plasticisers assist in providing a flexible, soft cured polyurethane in situ in the wound. Suitable plasticisers include medically acceptable mineral oils, silicone oils, vegetable oils, stearates, hydrogenated ethers and esters, and
20 mixtures thereof.

The optional humectants assist in maintaining the desired moist wound healing environment in situ in the wound. Suitable humectants include medically acceptable polyhydric alcohols such as glycerol, sorbitol, soft paraffin, urea
25 creams, lanoline, sodium pyrrolidone carboxylate (PCANa), gamma linolenic acid (evening primrose oil) and soya oil, tea tree oil, coconut oil (or any other nut oil), camomile, aloe vera, jojoba oil, cocoamide or mixtures thereof.

The optional hydrocolloids assist in adjusting the water absorbency and wicking properties of the cured polyurethane composition. Suitable hydrocolloids include alginates, pectin, gums such as guar gum or xanthan gum, modified celluloses such as carboxymethyl cellulose and hydroxyethyl cellulose, modified starches such as sodium starch glycolate, and mixtures thereof.

The optional blowing agents provide the cured polyurethane with a foamed or porous structure to increase its permeability to wound fluid. Suitable blowing agents include water (which reacts with isocyanate groups to form urea linkages) and carbon dioxide), and citric acid/sodium bicarbonate or formic acid or hydrofluorocarbon.

Preferably, the wound dressing compositions according to the invention have a curing time of from about 0.1 to about 180 minutes, preferably about 2 to about 30 minutes.

The optional siloxane wetting agents provide the cured polyurethane with increased wetting or wicking properties. Suitable surfactants include dimethyl siloxanes, PLURONICS (Registered Trade Mark of BASF), BRIJ (Registered Trade Mark of ICI) or mixtures thereof

In a second aspect, the present invention provides a wound dressing comprising a wound dressing composition according to the first aspect of the invention.

The wound dressing according to this aspect of the invention may further comprise reinforcing elements to assist removal of the cured polyurethane composition in one piece from the wound. Suitable reinforcing elements include woven or nonwoven fabrics, polymer webs or meshes. The reinforcing elements may be introduced into the wound cavity before, during or immediately after introduction of the partially cured polyurethane fluid.

The wound dressing according to the invention may further comprise drainage elements to assist drainage of exudate from wounds. Suitable drainage elements includes flexible polymeric tubes and flexible biodegradable tubes, such as those described in DE-A-4037931, the entire content of which is incorporated herein by reference.

In a third aspect, the present invention provides a wound dressing kit comprising: (a) a polyurethane prepolymer; and (b) a curing agent for the polyurethane prepolymer.

- 5 The components (a) and (b) are adapted to be used in combination to form a wound dressing composition according to the present invention. In certain embodiments, the components (a) and (b) are stored separately in a single package for mixing immediately before use. The package may comprise a barrier between the components that can be opened to allow the components to mix
- 10 inside the package immediately before use. In other embodiments, the package may comprise a mixing chamber for sterile mixing of the components immediately before use.

The wound dressing kit is adapted for the preparation of a wound dressing according to the invention by mixing of components (a) and (b). The kit may further comprise reinforcing elements and/or drainage elements as hereinbefore described. It may further comprise a secondary dressing for application over the wound dressing of the invention.

- 20 Preferably, both component (a) and component (b) are liquid at temperatures above 10°C, preferably at temperatures above 5°C, and more preferably at temperatures above 0°C. This assists mixing of the components at ambient temperatures.

25 Component (a)

Component (a) preferably comprises an isocyanate capped prepolymer.

Preferably, the isocyanate-capped prepolymer comprises from 0.1 to 1 meq NCO groups/g. In certain embodiments the isocyanate-capped prepolymer is an isocyanate-capped polyether or polyester prepolymer. For example, the prepolymer may be an isocyanate- capped oxyethylene/oxypropylene copolymer. This enables the properties of the polyurethane to be regulated by varying the

ration of ethylene oxide to propylene oxide in the prepolymer (high ethylene oxide gives a more hydrophilic product).

In certain embodiments, component (a) may be an isocyanate-capped castor oil,
5 or derivative thereof. For example, component (a) may be produced by reacting a diisocyanate such as isophorone diisocyanate (IPDI) with castor oil, or a glycerol mono- or diester of ricinoleic acid, or a derivative thereof produced by reaction with ethylene oxide or propylene oxide such as CASPOL 5001 or other ricinoleic acid derivatives such as CASPOL 5003

10 Preferably, the prepolymer is a reaction product of an aliphatic isocyanate, since polyurethanes manufactured from aliphatic isocyanates have superior mechanical properties and superior light stability. The isocyanates used in the prepolymer reaction can be selected from, but not limited to the following:

15 1,4 tetramethylene diisocyanate
1,6 hexamethyl diisocyanate (Bayer's Desmodur H)
Isophorone diisocyanate (IPDI)
Methylene bis(4-cyclohexyl)-isocyanate
Meta or para xylylene diisocyanate
20 Degussa's T-6040 (a mixture of IPDI and its trimer)
Isomeric mixtures of any of the above.

Commercially available isocyanate capped prepolymers include Degussa's Vestanat (Registered Trade Mark) EPU-937 prepolymer based on IPDI. Other 25 prepolymers could include the HYPOLOs (although not aliphatic, they would still work) and other aliphatic prepolymers based on H₁₂MDI (4,4'-dicyclohexylmethane diisocyanate) or CHDI (Trans 1,4-cyclohexane diisocyanate)

Component (a) may further comprise the plasticisers, humectants and
30 hydrocolloids.

Component (b)

A preferred polyol for preparation of the wound dressings and wound dressing kits according to the present invention is castor oil and other esters of ricinoleic acid 5 and its derivatives. One such derivative is a monoricinoleate ester to which either ethylene oxide or propylene oxide has been added to the hydroxyl group on the ricinoleate, available under the Registered Trade Mark CASPOL 5001.

It has been found that the branched structure of the castor oil and derivatives 10 thereof breaks up the symmetrical orientation of the polyurethane molecules, and allows the prepolymer to remain fluid at temperatures as low as 4°C. This provides further advantages in the preparation of fluid wound dressing compositions at ambient temperatures.

15 In certain embodiments, component (b) comprises water as a foaming and polymerising agent. The water in the component (b) reacts with the isocyanate prepolymer to cross-link the isocyanate groups in urea linkages and release CO₂, which causes the polyurethane reaction mixture to form a foam. Preferably, the amount of water in the component (b) is from 0.02 to 0.1 parts by weight per part 20 by weight of the isocyanate prepolymer.

In certain embodiments, component (b) comprises chain extending or terminating agents, catalysts or mixtures thereof. For example, component (b) may comprise diamine chain extending/terminating compounds such as 1,4-butane diol, 1, 5- 25 pentane diol or 1,6-hexane diol or diamines such as DDM (4, 4' diaminodiphenylmethane) or DAB (1, 3 diaminobenzene)

In certain embodiments, component (b) further comprises a catalyst for the polymerisation, preferably a diamine such as diazobicyclo octane or 30 dimethylaminoethyl ether. Preferably, the catalysts are present in component (b) in an amount of 0.005 to 0.02 parts by weight, based on one part by weight of the isocyanate prepolymer. Catalysts such as tertiary amines and organometal compounds, most preferably organotin catalysts may also be present. The

catalyst to be employed should be a non-cytotoxic catalyst, for example one of the catalysts listed in US Patent 4,332,927, the entire content of which is incorporated herein by reference. For example, an organotin derivative made with castor oil.

- 5 In certain embodiments, the component (b) comprises a polyurethane or polyurea chain terminating compound, preferably selected from monohydric alcohols and amines. More preferably, the component (b) comprises a mixture of mono-amines and diamines. The amounts of chain extending and terminating compounds influence the physical properties of the foam. In particular, amine/diamine chain
- 10 terminating/extending compounds react with the prepolymer very much faster than water and alcohols. For example, the tackiness of the foam increases with increasing monohydric alcohol or monoamine content in component (b). Preferably, the chain extending and terminating compounds are present in component (b) in an amount of 0.05 to 0.4 parts for alcohols and 0.01 to 0.05 parts
- 15 for the amines, based on one part by weight of the isocyanate prepolymer.

The blowing agents and surfactants may also be present in component (b)

- Component (b) may comprise wound therapeutic materials. Suitable therapeutic materials include: antiseptics such as molecular silver, silver sulfadiazine or chlorhexidine; pain relieving agents such as lignocaine; anti-scarring agents such as mannose-6-phosphate, and agents for promoting wound healing such as growth factors.

- 25 In a further aspect, the present invention provides the use of components (a) and (b) as hereinbefore described for the preparation of a wound dressing composition comprising a partially cured polyurethane fluid for application directly to a wound as a wound dressing. Preferably, the wound dressing composition is a composition according to the first aspect of the present invention.

30

The present invention further provides a method of treatment of a wound comprising applying thereto a wound dressing composition comprising a partially cured polyurethane fluid. Preferably, the wound dressing composition is a

composition according to the first aspect of the present invention. Preferably, the composition is applied so as to substantially completely fill the wound. The composition is allowed to cure in the wound.

- 5 It will be appreciated that any features that are described as optional or preferred in connection with any one aspect of the present invention are likewise optional or preferred in connection with any other aspect of the invention. Thus, for example, the components (a) and (b) described in connection with the kits according to the present invention may be mixed to prepare a wound dressing composition
- 10 according to any embodiment of the first aspect of the invention.

Specific embodiments of the present invention will now be described further, by way of example. In the examples, the following abbreviations and trade names are used:

- 15 VESTANAT (Degussa) A prepolymer based on isophorone diisocyanate.
- T-6040 (Degussa) A mixture of isophorone diisocyanate and its trimer
- EPU-937 (Degussa) A prepolymer based on isophorone diisocyanate.
- CASPOL 5001 (CasChem) A dihydroxy castor oil derivative
- 20 ACCLAIM (Bayer) A polypropylene glycol
- VORANOL (Dow) A polyol
- COTIN (CasChem) A proprietary urethane catalyst
- POLY G 55-53 (Arch) A PEO/PPO polyol containing 27% ethylene oxide.
- AVICEL
- 25 AC-DI-SOL
- Purity Gum 59 A low viscosity starch derived from waxy maize
- SAFOAM B A sodium hydrogen carbonate or sodium bicarbonate

Example 1

30

In order to reduce the initial concentration of available NCO in the wound dressing below 3.8%, a prepolymer was prepared as follows.

The prepolymer was prepared by reacting a mixture of Glycerol based polyether polyol (Poly-G-76-120) and a hydroxy terminated polyoxyalkylene polyol (Poly-G-55-56) with VERSANAT IPDI and sufficient catalyst (Cotin1707) to form the desired prepolymer.

5

The prepolymer had an NCO content of less than 5% resulting in a lower initial NCO value of the final wound dressing.

A wound dressing was made using the prepolymer prepared above in component

10 (a). A dressing was prepared using two different methods: (1) mixing the components and pouring the mixture into a plastic cup and (2) mixing the components and coating the mixture onto a release liner. After curing, the coated film was stripped from the release liner and die cut into ribbon and various other shapes. An attractive, sponge-like product was obtained. The strips exhibited
15 very good mechanical integrity both wet and dry.

The components of the representative product are as follows:

Caspol 5003	23%
Castor Oil	6
Poly G 55-56	10.5
T-6040	16
EPU-937	15
Soybean Oil	4
Purity Gum 59	4
Avicel	17
Ac-di-Sol	<1
Cotin 1707	<1
Citric Acid	<1
NaCarbonate	<1
Safoam B	<1

This composition can be adjusted to obtain a softer wound dressing. The composition of the above formulation is used here as an example to demonstrate the isocyanate concentration of an initial prototype composition as a function of time.

5

The measured free NCO of the prepolymer before final compounding was less than 5%. It should be kept in mind that the formulation is catalysed, and when the catalysed and un-catalysed portions are mixed together, reaction quickly occurs. Accordingly, available NCO was determined by titration immediately after mixing,

10 and also after 15 and 30 minutes. The data is presented in the following table:

TIME (MINUTES)	%NCO
Theoretical	Less than 5.0
Actual Initial	2.7
15	0.6
30	<0.1

Replacement of the glycol present in EPU-937 with a larger molecular weight glycol reduces the NCO content even further.

15

Tensile strengths are quite remarkable. Initial data generated on drawn down samples prepared from the polymer in the previously described example indicate that tensile was greater than 2,000 grams per inch width sample. After water immersion for 24 hours, the loss of tensile strength is less than 10%.

20

The above example has been described by way of illustration only. Many other embodiments falling within the scope of the accompanying claims will be apparent to the skilled reader.

25

CLAIMS

1. A wound dressing composition comprising a partially cured polyurethane fluid.
- 5 2. A wound dressing composition according to claim 1, wherein the composition comprises at least 50% by weight of polyurethane components,
- 10 3. A wound dressing composition according to claim 1 or 2, wherein the composition has been prepared by mixing a diisocyanate or a polyisocyanate component with a diol or polyol component
- 15 4. A wound dressing composition according to claim 3, wherein at least 10% of the isocyanate groups originally present in the isocyanate component are still unreacted in the wound dressing composition.
- 20 5. A wound dressing composition according to any preceding claim, wherein the absolute amount of unreacted isocyanate in the wound dressing composition is less than about 4wt.%.
- 25 6. A wound dressing composition according to any preceding claim, further comprising an additives selected from the group consisting of humectants, plasticisers, hydrocolloids, blowing agents, medicaments, and mixtures thereof.
7. A wound dressing composition according to any preceding claim, wherein the composition has a curing time at 25°C of from about 0.1 to about 100 minutes.
- 30 8. A wound dressing comprising a wound dressing composition according to any of claims 1 to 7.
9. A wound dressing according to claim 8, further comprising reinforcing elements to assist removal of the cured polyurethane composition in one piece from a wound.

10. A wound dressing according to claim 8 or 9, further comprising drainage elements to assist drainage of exudate from wounds.
- 5 11. A wound dressing kit comprising: (a) a polyurethane prepolymer; and (b) a curing agent for the polyurethane prepolymer, as a combined preparation.
12. A wound dressing kit according to claim 11, wherein the components (a) and (b) are stored separately in a single package for mixing immediately before
10 use.
13. A wound dressing kit according to claim 12, wherein package comprises a barrier between the components that can be opened to allow the components to mix inside the package immediately before use.
15
14. A wound dressing kit according to claim 12 or 13, wherein the package comprises a mixing chamber for sterile mixing of the components immediately before use.
- 20 15. A wound dressing kit according to any of claims 11 to 14, further comprising one or more of the group consisting of reinforcing elements, drainage elements, and a secondary dressing.
16. A wound dressing kit according to any of claims 11 to 15, wherein
25 component (a) and component (b) are both liquids at temperatures above 5°C.
17. A wound dressing kit according to any of claims 11 to 16, wherein component (a) comprises an isocyanate capped prepolymer.
- 30 18. A wound dressing kit according to claim 17, wherein the prepolymer is prepared by reacting a diisocyanate with compound selected from the group consisting of castor oil, other esters of ricinoleic acid, and derivatives thereof.

19. A wound dressing kit according to any of claims 11 to 18, wherein the diol or polyol is selected from the group consisting of castor oil, other esters of ricinoleic acid, and derivatives thereof.

5 20. A wound dressing kit according to any of claims 11 to 19, wherein component (b) comprises a wound therapeutic material selected from the group consisting of antiseptics such as molecular silver, silver sulfadiazine or chlorhexidine; pain relieving agents such as lignocaine; anti-scarring agents such as mannose-6-phosphate, and agents for promoting wound healing such as
10 growth factors, and mixtures thereof.

21. Use of (a) a polyurethane prepolymer; and (b) a curing agent for the polyurethane prepolymer, in combination for the preparation of a wound dressing composition comprising a partially cured polyurethane fluid for application directly
15 to a wound as a wound dressing.

ABSTRACT

FLUID WOUND DRESSING

5 A wound dressing composition comprising a partially cured polyurethane fluid. The composition can be injected directly into a wound, where it cures to form a wound filling dressing. Also provided is a wound dressing comprising such a composition. Also provided is a kit for the preparation of such wound dressings, the kit comprising (a) a polyurethane prepolymer; and (b) a curing agent for the
10 polyurethane prepolymer. Preferably, the polyurethane components comprise reaction products of a diisocyanate with castor oil or a related ester of ricinoleic acid or its derivatives.

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